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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,136	07/28/2003	Ben A. Hitt	CORR-004/02US	4523

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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,136

Applicant(s)

HITT ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/13/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/13/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are currently pending.

Priority

The benefit of priority to US Provisional Application 60/398,831 (29 July 2002) is hereby denied. The priority application does not contain teachings with regard to the dilution parameters as in the instant claims.

Information Disclosure Statement

The Information Disclosure Statement filed 13 November 2003 has been considered. A signed copy of PTO Form 1449 is included with this Office Action.

Claim Objections

Claim 25 is objected to because of the following informalities: Claim 25 is awkwardly worded. Perhaps Applicant intends the claim to read "the method of claim 24, wherein the diluted first serum and the diluted second serum are ionized by the same electrospray ionization process". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-26 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The methods of claims 1-26 are not supported by a specific asserted utility or

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a well-established utility. The claimed methods are directed to selecting sera from a control group and a test group and performing mass spectrometry in order to map the test to the control. However, there is no specific utility set forth such that this result is immediately useful. The specification states that the method is performed such that further analysis can then be done on the samples (page 3, paragraph [0012]). This does not constitute a specific utility, as set forth under 35 USC 101. Applicant is reminded that a "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. In the instant case, determining whether a test spectrum maps to a model does not constitute a specific utility.

Claims 1-26 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial or well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “determining whether the test spectrum obtained from said performing maps to the control model”. It is unclear what is intended by “maps”. Does this mean that the test spectrum is compared to the control spectrum or is the test spectrum physically mapped to the control spectrum. Clarification is requested.

Claim 2 recites “selecting a cluster”. It is unclear from where the cluster is selected or what the cluster represents. Is the cluster selected from an area with the greatest number of spectra? Clarification is requested.

Claim 5 recites “and the diluent is a first diluent”. It is unclear if Applicant intends this to be the diluent from the test or from the control. Clarification is requested.

Claims 15 and 24 recite “determining whether the diluted test serum produces a spectrum within a predetermined tolerance”. The metes and bounds of a “predetermined tolerance” or “predetermined criteria” are not defined. It is unclear what the tolerance or criteria represent. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 7, 10, 12, 13, 15, 17, 20, 21, and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Petricoin et al. (Journal of the National Cancer Institute (2002) Vol. 94, No. 20, pages 1576-1578), as supported by Xiao et al. (Cancer Research (2001) Vol. 61, pages 6029-6033) (reference 2 in Petricoin pointed to for the SELDI technique).

Petricoin et al. teach a method for analyzing serum proteomic patterns for detection of prostate cancer using mass spectra and clustering techniques. In regard to claims 1, 12, 15, and 17 Petricoin et al, teach selecting a group of sera from men without prostate cancer and men with prostate cancer and performing mass spectrometry on the samples. These were matched against patterns revealed by a training set (abstract). The mass spectrometry techniques employed was SELDI-TOF, in which Xiao et al have described in further detail to include dilution of samples at various concentrations on page 6030, column 1).

In regard to claim 2, Petricoin et al. teach that the sera were applied to a protein chip and that an analytical tool combining a genetic algorithm and clustering techniques to define a pattern (page 1576, column 3, paragraph 2).

In regard to claims 5 and 13, Petricoin et al. teach classifying a biological state (cancer or benign) from the spectrum (page 1577, paragraph 2).

In regard to claim 7, the pool of sera consists of sera from healthy males and sera from males with prostate cancer (abstract).

In regard to claims 10, 20, 21, and 23, Xiao et al, teach that the diluent is one of a plurality of diluents (page 6030, column 1).

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Claims 1, 2, 3, 5, 7, 10, 12-17, 20, 21, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Adam (PTO 1449 reference 19; Cancer Research (2002) Vol. 62, pages 3609-3614).

Adam et al. teach a method in which a protein chip surface enhanced laser desorption/ionization mass spectrometry approach is coupled to a learning algorithm to differentiate prostate cancer from noncancer samples (abstract). In regard to claims 1, 2, 12, 15, 24, and 25 Adam et al. teach a system in which SELDI-TOF detects proteins bound to a protein chip array. Serum samples are taken from patients diagnosed with PCA, BPH, and from healthy males (control). Mass spectra was generated from the various samples and a peak alignment (cluster) was performed. A classification of the groups was also performed to place the samples against a training set (see Material and Method; pages 3609-3611).

In regard to claims 3, 17, 20, 21, and 23 Adam et al. teach dilution of samples at page 3610, column 1, SELDI profiling section.

In regard to claims 5 and 13 Adam et al. teach a predetermined biological state at page 3610, column 2, data analysis section.

In regard to claim 7, Adam et al. teach at least two types of sera (PCA and BPH)(see above).

In regard to claims 10, the diluents are at least one of a plurality (page 3610, column 1, SELDI profiling section.

In regard to claims 14 and 16, the serum are diluted with acetonitrile (page 3610, column1, SELDI profiling section.

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Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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September 29, 2005
Lori A. Clow, Ph.D.
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Lori A. Clow

**MARJORIE A. MORAN
PRIMARY EXAMINER**

Marjorie A. Moran
9/29/05